

## **REMARKS**

Claims 1-25 are pending in the application.

### *Allowable Subject Matter*

Claims 18-25 were indicated allowable if amended to independent form. Claim 18 has been amended to independent form and claims 19-25 remain dependent thereon. Confirmation of the allowance of claims 18-25 is respectfully requested.

### *Claim Rejections under 35 U.S.C. § 103*

Claims 1-25 (understood to be claims 1-17 since claims 18-25 were indicated allowable) were rejected under 35 U.S.C. 103 (a) as being unpatentable over Napro, WO 0049006 ("Napro") in view of Breslow et al., Tetra. Let. Vol. 39 no. 19 pp 2887-2890 ("Breslow") and Damen et al., US 5,874,595 (Damen). The applicant respectfully traverses.

The present application relates to a process for the preparation of synthetic taxanes comprising the step of protecting 7-OH selectively with a lanthanon compound.

Napro discloses an intermediate for the production of paclitaxel, wherein the OH at C-7 position of the intermediate is protected selectively by a potassium counterion or a sodium counterion. The examiner alleges that it is possible to use alkali bases other than KOH or NaOH to form the corresponding C7 metal oxide of baccatin III. However, the properties of lanthanide salts are highly different from those of potassium or sodium counterions, and there is no evidence in the prior art showing that they are similar with respect to the selective protection of C(7)-OH of taxanes. Accordingly, there is no motivation for a person skilled in the art to apply lanthanide salts in selective protection of C(7)-OH of taxanes from Napro.

Breslow discloses a method for synthesis of metalloporphyrin wherein the sites of androstanediol can be hydroxylated selectively. The teachings of Breslow are totally irrelevant to the selective protection and acylation of the sites on taxanes.

Damen discloses a method for the preparation of baccatin III wherein 10-deacetylbaccatin III is selectively acylated to baccatin III by Lewis acids, e.g., Lewis acids of lanthanon. However, the role of lanthanon in Damen is to catalyze the selective acylation and does not involve the selective protection of C(7)-OH of taxanes. In fact, in Damen, the 7-OH of the raw material has been protected before the acetylation of 10-OH (see scheme 2 in column 4, claims etc.), which demonstrates that the Lewis acid in the process of Damen is irrelevant to the selective protection of C(7)-OH.

In view of the foregoing, it is respectfully submitted that there is no teaching, suggestion or motivation in the cited references, alone or in combination, for a person skilled in the art to selectively protect the C7-OH on a taxane raw material bearing side chains comprising C(7)-OH, C(10)-OH and C(13) having C(2')-OH with a lanthanon compound when preparing synthetic taxanes, as claimed.

Furthermore, as previously noted, the effect of the present invention is not predictable from the prior art. It would have been unexpected at the time the invention was made that lanthanon compounds would have high selectivity for C(7)-OH in the paclitaxel parent nucleuses, and hardly react with C(2')-OH and C(10)-OH. And there is no suggestion in the prior art that such a process would increase the yield of the principal product, C(10)-acetyl taxane, as disclosed in the present application.

Accordingly, it is respectfully submitted that the pending claims are non-obvious and are patentable over the cited art, and withdrawal of the rejections under 35 U.S.C. §103 is respectfully requested.

### *Conclusion*

Applicants believe that all pending claims are allowable and respectfully request a Notice of Allowance for this application from the Examiner. The claim amendments are without prejudice to the subsequent prosecution of previously presented claims or other subject matter disclosed in the application in one or more continuation or further divisional applications.

Should the examiner believe that a telephone conference would expedite the prosecution of this application, applicant's attorney requests that the examiner contact him at the telephone number below.

Applicants hereby petition for any extension of time that may be required to maintain the pendency of this case, and any required fee for such extension or any further fee required in connection with the filing of this amendment is to be charged to Deposit Account No. 504480 (Order No. CPALP006).

Respectfully submitted,  
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